

Phenix™ Vertebral Body Replacement 510(k) Application

OCT 15 2007

**Company:**

Company Name  
Street address  
City, State Zip Code  
Telephone

Spinal Devices, LLC  
1155 Allgood Road, Suite 6  
Marietta, GA 30062  
770-874-0935

**Company Contact:**

Tim Lusby

**Common Name**

Spinal vertebral body replacement device

**Trade Name:**

Phenix™ VBR

**Classification:**

Class II

**Product Code:**

MQP, 888.3060

**Device Description:**

The Phenix™ VBR is a rectangular implant with an open center comprised of titanium, (Ti-6Al-4V). The Phenix™ VBR's superior and inferior ends have ridges to interface with the vertebral endplates to resist rotation and migration. The implant is available in a range of sizes, as well as flat and lordotic angled implants to accommodate variations in patient's anatomy. The Titanium allows for radiographic visualization.

**Intended Use:**

The Phenix™ VBR is a vertebral body replacement device intended for use in the thoracic spine (i.e., T1-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy) due to tumor or trauma (i.e., fracture). The Phenix™ VBR is designed to restore the mechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The Phenix™ VBR is intended for use with supplemental spinal fixation systems that have been labeled for use in the thoracic spine. The interior of the Phenix™ VBR may be packed with bone graft.

**Predicate Device:**

Based on the same indications for use, intended use, design and performance to the predicate device, substantial equivalence was determined.

**Performance Data:**

Testing was completed to characterize the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

New Business Development, LLC  
% Mr. Tim Lusby  
General Manager, Member  
1155 Allgood Road, Suite 6  
Marietta, Georgia 30062

OCT 15 2007

Re: K072029  
Trade/Device Name: Phenix Vertebral Body Replacement  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: MQP  
Dated: August 31, 2007  
Received: September 4, 2007

Dear Mr. Lusby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large, stylized "M" at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**Indication for Use Statement**

510(k) Number (if known): K072029

Device Name: Phenix™ Vertebral Body Replacement

Indications for Use:

The Phenix™ VBR is a vertebral body replacement device intended for use in the thoracic spine (i.e., T1-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy) due to tumor or trauma (i.e., fracture). The Phenix™ VBR is designed to restore the mechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The Phenix™ VBR is intended for use with supplemental spinal fixation systems which are labeled for use in the thoracic spine. The interior of the Phenix™ VBR may be packed with autograft bone.

Prescription Use   X   or Over-The-Counter Use

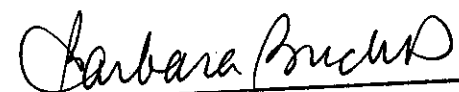
(21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K072029